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Two-Year Outcomes Following Platinum Chromium Everolimus-Eluting Stent Implantation in Small Vessel Lesions in Japan

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Background: Small vessel diameter is associated with increased restenosis rates and adverse outcomes following coronary stenting. The PLATINUM Japan Small Vessel multicenter study specifically assessed small vessel stenting in Japanese patients treated with the PROMUS Element everolimus-eluting stent (Boston Scientific, Natick, MA). Follow-up beyond 1 year has not been reported previously.

Methods: Patients with a single de novo target lesion ≤ 28 mm long and ≥ 2.25 to <2.50 mm in diameter were eligible for treatment with a 2.25 mm diameter PROMUS Element stent.

Results: A total of 60 patients were enrolled at 14 clinical sites; 32 patients were randomized to receive routine angiography following the 1-year clinical follow-up (angiography was completed in 29 patients). Patients were 69.2 ± 9.8 years of age, 68.3% male, and 36.7% had medically treated diabetes. Average baseline reference vessel diameter was 2.02 ± 0.26 mm. Technical success and procedural success were both 100% (60/60). Post-dilation was used in 70.0% with a 16.6 atm average pressure. Dual antiplatelet treatment was used in 78.3% of patients at 2 years post-procedure. Two-year clinical follow-up is complete in 100% of patients. Through 365 days post-procedure, there were no major adverse cardiac events. In-stent late loss was 0.18 ± 0.30 mm in the angiographic subset. Following angiographic assessments (366-396 days post-procedure) target lesion revascularization (TLR) occurred in 2 patients (including 1 patient in the angiographic subset); there were no additional TLRs through the 2-year follow-up. Target vessel revascularization outside the target lesion occurred in 3 patients through the 2-year follow-up. One patient (1.7%) experienced a non-Q-wave myocardial infarction (MI) in the target vessel 413 days post-procedure. There were no Q-wave MIs or stent thromboses through 2 years.

Conclusion: The results support the safety and efficacy of the PROMUS Element 2.25 mm stent in Japanese patients.

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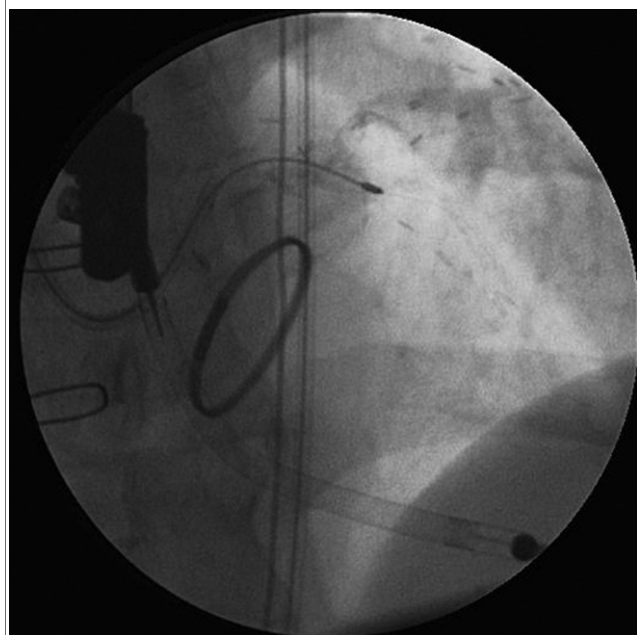
Drug Eluting Balloon for De-Novo, In stent Restenosis and Bifurcation Lesions of Coronary Artery Disease: Short and Intermediate Results, Prospective Registry

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Objectives: This prospective study designed to assess the safety and short and intermediate term efficacy of drug eluting balloon (DEB) in the treatment of de-novo, in-stent restenosis and bifurcation coronary artery disease (CAD) in Saudi Arabic Population.

Methods: Total of 64 patients so far enrolled in a prospective registry using a Be Brown Paclitaxel-coated balloon (DEB) at our hospital, 61 patients were studied for short and intermediate term outcomes (6 to 12 months). All patients with symptomatic CAD requiring percutaneous intervention (PCI) with DEB were included. Clinical follow-up was conducted at 6 to 12 months. Coronary angiography (CAG) or SPECT Scan were done in 70% of patients during this period. Primary outcome was a composite of target vessel revascularization and mortality.

Results: Procedural success was achieved in 96% of the patients. Two patients were failed due to failed DEB to cross heavily calcified vessel. Mean age was 60.8 ± 30 years. 47 patients (77%) presented with stable angina and 9 patients 15% with acute coronary



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Long term Outcomes of Patients Treated With The Paclitaxel- Versus The Everolimus -eluting Stents in a Consecutive Cohort of Patients at a Tertiary Medical Center

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Background: In this study we compare the outcomes of the paclitaxel-eluting stent (PES) versus the everolimus-eluting stent (EES) treated patients at a tertiary medical center and up to two years follow up.

Methods: Unselected consecutive patients were retrospectively recruited following stenting with PES (159 patients) or EES (189 patients). The first 100 consecutive patients in each cohort underwent syntax scoring. The primary endpoint of the study was target lesion failure (TLF) defined as the combined endpoint of cardiac death, non fatal myocardial infarction or target lesion revascularization (TLR). Secondary endpoints included target vessel revascularization (TVR), target lesion revascularization (TLR), target vessel failure (TVF), acute stent thrombosis (ST), total death, cardiac death, and non fatal myocardial infarction (MI). Analysis was performed with patient number as the denominator.

Results: The syntax scores in the 2 groups were similar (20.3 ± 13.9 vs 20.4 ± 13.8 , $p=0.97$). Patients treated with the PES stent had less congestive heart failure and restenotic lesions, but a higher prevalence of longer lesions, non left main bifurcations, and required more stents per patient (4.3 ± 2.8 vs. 2.9 ± 2.1). The primary unadjusted outcome of TLF occurred in 29.3% PES vs 20.3% EES ($p=0.059$). The secondary unadjusted endpoints for PES vs EES respectively were: TVF 36.7% vs 28.0% ($p=0.106$), TVR 35.7% vs 26.5% ($p=0.079$), definite and probable ST 1.2% vs 1.6%, non fatal MI 4.5% vs. 4.2%, and cardiac mortality 5.6% vs 3.2%. A propensity matched analysis showed no significant difference in the primary endpoint of TLF ($28.6\% \pm 16$ vs $24.6\% \pm 14$, $p=0.67$) in PES vs EES respectively.

Conclusion: Using unadjusted analysis, EES had lower TLF than PES in a broad cohort of patients and lesions undergoing PCI. However, when baseline differences between the 2 cohorts were adjusted for, similar efficacy between the PES and EES was seen at 2 years follow-up.